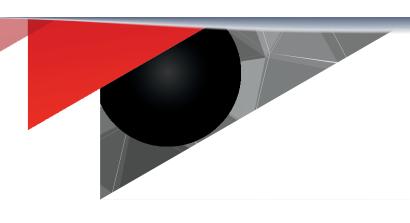
### MISSOURI BOARD OF PHARMACY



# ANNUAL REPORT



FY 2024



Mike Kehoe, Governor State of Missouri

Angela L. Nelson, Director Department of Commerce and Insurance

Sheila Solon, Division Director Division of Professional Registration





Mike Kehoe Governor State of Missouri

### Sheila Solon, Division Director DIVISION OF PROFESSIONAL REGISTRATION

Department of Commerce and Insurance Angela L. Nelson, Director

MISSOURI BOARD OF PHARMACY 3605 Missouri Boulevard P.O. Box 625 Jefferson City, MO 65102-0625 573-751-0091 PHONE 573-526-3464 FAX 800-735-2966 TTY Relay Missouri 800-735-2466 Voice Relay Missouri

Kimberly A.
Grinston Executive Director
www.pr.mo.gov/pharmacist
s email:
MissouriBOP@pr.mo.gov

To The Honorable Governor Mike Kehoe:

In compliance with § 338.140.3, RSMO, the Missouri Board of Pharmacy is pleased to submit its Annual Report which contains the proceedings of the Board for the fiscal year ending June 30, 2024 ("FY24"). The Board's mission is to protect the public in the regulation of pharmacy practice. The Board of Pharmacy is pleased to report another successful year.

Respectfully yours, MISSOURI BOARD OF PHARMACY By:

Kimberly Grinston Executive Director



# Department of Commerce and Insurance Division of Professional Registration Missouri Board of Pharmacy

#### FY 2024

#### **Board Members**

James Gray, PharmD., President
Christian Tadrus, PharmD., Vice-President
Colby Grove, PharmD., Member
Darren Harris, R.Ph., Member
Douglas Lang, R.Ph., Member
Tammy Thompson, R.Ph., Member
Anita K. Parran, Public Member

#### Missouri Board of Pharmacy

P.O. Box 625
3605 Missouri Boulevard Jefferson
City, Missouri 65102 Phone (573)
751-0091
Fax (573) 526-3464
Web Site http://www.pr.mo.gov/pharmacists
Email: MissouriBOP@pr.mo.gov

Kimberly A. Grinston, J.D., Executive Director

### TABLE OF CONTENTS



Executive Summary	5
About the Board	7
Board Operations	8
Financial Summary	11
Licensing	13
Complaint Summary	25
Disciplinary Actions	28
Inspections/Investigations	32
Compounded Drug Testing	34
Rulemaking	35
Rx Cares for Missouri	36

### **Executive Summary**



This Annual Report covers the activities of the Missouri Board of Pharmacy from July 1, 2023, to June 30, 2024 (FY24). The Board is pleased to announce another successful regulatory year as reflected below:

#### **Board Operations**

- The Board held nineteen (19) meetings during FY24, including sixteen (16) regular meetings, one (1) email ballot meeting, and (2) Sterile Compounding Sub-Committee meetings. In addition to Board meetings, the Missouri Hospital Advisory Committee established by § 338.165, RSMo, held one (1) virtual meeting facilitated by the Board. Board Members Douglas Lang and Christian Tadrus also serve on the Joint Oversight Task force for the Prescription Drug Monitoring Program.
- As part of its ongoing efforts to protect patients through voluntary compliance, the Board hosted five (5) education webinars. Webinars were free and Board approved for pharmacist continuing education.

#### **Financial Overview**

- The Board's total appropriation and authorized transfers for FY24 were \$4,257,747. Board expenditures increased 12.43% to \$3,272,261.79, attributable to additional personal service costs related to the statewide employee salary plan.
- Board revenue decreased in FY24 by 16.8% to \$3,045,998.74, in contrast to an uncharacteristic revenue increase in FY23 related to new application revenue affiliated with a national chain expansion. The decrease aligned with previous revenue history.

#### **Licensing Summary**

- The Board's total licensee/registrant count remained consistent with 37,973 licensees/registrants at the close of the fiscal year (-0.5%), as reflected below:
  - o Drug Distributors (licensed & temporary) 1,281 (-4.6%)
  - Drug Distributor Manufacturer Registrants 119 (+19%)
  - o Drug Outsourcers 48 (-2%)
  - Intern Pharmacists 1,337 (+5.7%)
  - Pharmacists (active and inactive) 12,277 (+3.75%)
  - o Pharmacists (temporary) 10 (- 9%)
  - Pharmacies (instate, non-resident and temporary) 2,805 (-1.3%)
  - Pharmacy Technicians 20,147 (-.23%)
  - Third-Party Logistics Provider (licensed & temporary) 249 (+3.3%)
- New licensees/registrations remained stable with a total of 6,669 new licensees/registrants issued in FY24 (-1.2%) as reflected below:
  - o Drug Distributors (91, +2.2%)
  - Drug Distributor Registrants (28, +366.6%)
  - Drug Outsourcers (5, No Change)
  - o Intern Pharmacists (322, -10.3%)
  - o Pharmacies (233, -33.4%%)
  - o Pharmacists (Active and Inactive) (444, -2.8%)
  - Pharmacy Technicians (5,510, +1.3%)
  - Temporary Pharmacists (8, -12.5%)
  - Third-Party Logistics Providers (28, -28.2%)
- Total pharmacies decreased by 1.3% (1,427 in-state, 1,376 non-resident, 2 temporary). In-state pharmacies

### **Executive Summary**



decreased by 1.1%; Non-resident pharmacies increased by 3.6%.

• Two (2) Missouri counties do not have a licensed pharmacy (Schuyler & Knox); Sixteen (16) Missouri counties have only one licensed pharmacy.

#### Complaint Handling

- The Board received/opened 919 new complaints in FY24, representing an 81.2% increase from FY23. The
  increase is partially attributable to pharmacist continuing education audit cases opened after the FY23
  pharmacist renewal year (288, 31.3%). No tax compliance cases/complaints were referred from the
  Missouri Department of Revenue during the fiscal year.
- The Board issued final dispositions on 829 complaints/cases in FY24. All of the closed complaints/cases were non-tax related.
- Of the 829 non-tax related complaint dispositions, 91.8% resulted in no disciplinary action (761 cases), while disciplinary action was taken in the remaining 8.2% (68 cases).

#### **Disciplinary Actions**

 The Board issued sixty-eight (68) practice related disciplinary actions in FY24, representing a minor 1.49% increase from FY23.

#### Inspections/Investigations

- 1,076 regulatory inspections were conducted during the fiscal year (+4%). Approximately 63.6% of Board inspections resulted in regulatory violations (violations noted/compliance notices).
- Completed investigations decreased by 13.6% to 246 completed investigations during the fiscal year.

#### Compounded Drug Testing

• Pursuant to § 338.150, RSMo, the Board conducts a testing program for drug preparations compounded by licensed pharmacies. 71.2% of products tested in FY24 were satisfactory, while 28.8% were unsatisfactory. Failing potency results ranged from 40.6% to 126.7%.

#### Rulemaking

- The Board continued its review of Missouri's pharmacy rules to ensure appropriate and consistent regulation.
- Five (5) administrative rules were adopted or amended in FY24 (new, amendment, and emergency). The board submitted one (1) legislative proposal for approval by the Governor to clarify/expand authorized pharmacist services to address a public health need.

#### Rx Cares for Missouri

- The Board expended \$368,430.88 for the Rx Cares for Missouri Program in FY24: \$149,862.85 in Rx Cares grant funding/educational activities and \$181,499.53 for the Rx Cares medication destruction/disposal program.
- One-hundred and twenty-four (124) entities were approved to participate in the medication destruction/disposal program in FY 24, including, pharmacies, hospitals, and local law enforcement agencies\*\*
- Approximately 14,650.4 pounds of unwanted medication were destroyed in FY24 (-5.5%); A total of 51,476.96 pounds of unwanted medication have been destroyed since program inception.\*\*

### About the Board



#### Mission Statement

The Board's mission is to serve and protect the public by providing an accessible, responsible and accountable regulatory system that:

- Protects the public from incompetence, misconduct, gross negligence, fraud, misrepresentation or dishonesty;
- Licenses only qualified and competent professionals, and;
- Ensures compliance with professional standards and federal and state pharmacy law.

#### ABOUT THE MISSOURI BOARD OF PHARMACY

The Missouri Board of Pharmacy was statutorily created in 1909 and has served the citizens of Missouri through the regulation of pharmacy practice for over 100 years. The Board of Pharmacy is an autonomous Board within the Division of Professional Registration, an agency of the Department of Commerce and Insurance.

#### **MEMBERSHIP**

The Board consists of seven (7) members, including, six (6) licensed pharmacists actively engaged in the practice of pharmacy and one (1) public member. By statute, at least one member must provide pharmaceutical services to a hospital, skilled nursing facility or intermediate care facility on a full-time basis. Board members are appointed by the Governor and confirmed by the Missouri Senate. All members hold office for five (5) years from the date of their appointment or until their successors have been appointed and qualified. The Board annually elects a president and vice-president, each of whom serve one (1) year terms.

#### **FUNCTIONS**

Pursuant to Chapter 338, RSMo, the Board has superintending control over the practice of pharmacy in the State of Missouri and its primary duties consist of:

- Ensuring compliance with Chapter 338, RSMo, and the rules of the Board;
- Licensing/registering pharmacists, pharmacy technicians, intern pharmacists, pharmacies, drug distributors, drug outsourcers and third-party logistics providers;
- Investigating complaints within the Board's statutory jurisdiction;
- Disciplining licensees which may include, public censure, probation, suspension or revocation of a licensee/ registrant;
- Inspection of pharmacies, drug distributors, drug outsourcers and third-party logistics providers; and
- Approval of preceptors and intern training facilities.

### **Board Operations**



#### **General Board Operations**

The Board held nineteen (19) meetings during FY24, including sixteen (16) regular meetings, one (1) email ballot meeting, and (2) Sterile Compounding Sub-Committee meetings.\* In addition to Board meetings, the Missouri Hospital Advisory Committee established by § 338.165, RSMo, held one (1) virtual meeting facilitated by the Board.\* Board Members Douglas Lang and Christian Tadrus also serve on the Joint Oversight Task force for the Prescription Drug Monitoring Program.

\*Public attendees were able to virtually attend open session meetings.

#### Staff

The following staff were employed by the Board at the close of FY24:

#### Staff

- Kimberly Grinston, J.D., Executive Director
- Jennifer Boehm, Administrative Coordinator
- Semaja Smith, Pharmacy Technician Coordinator
- Kim Hatfield, Compliance Coordinator
- Sara Jones, Customer Service Representative
- Erika Wright, Pharmacist Coordinator

#### Inspectors

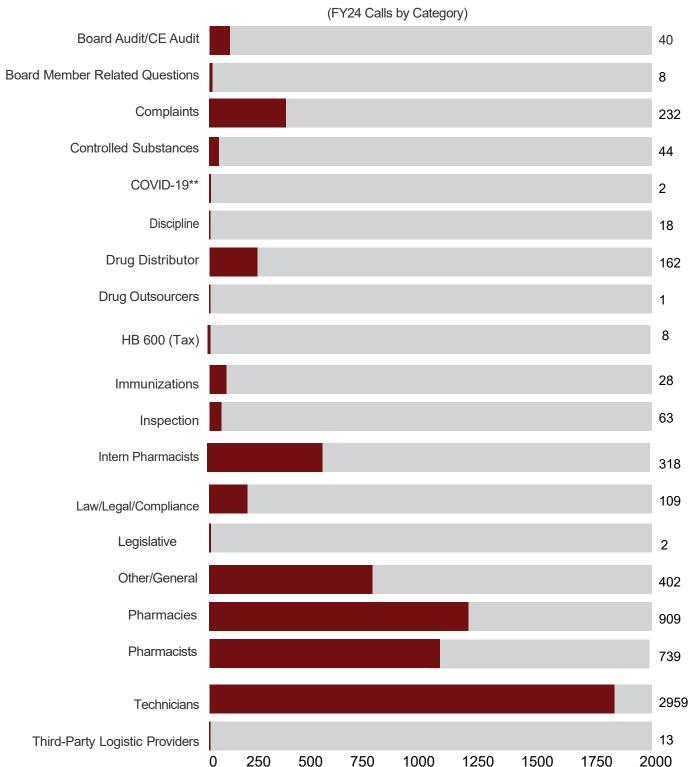
- Tom Glenski, R.Ph., Chief Inspector
- Katie DeBold, PharmD.
- Andrea "Andi" Miller, PharmD.
- Scott Spencer, R.Ph.
- Lisa Everett, R.Ph.
- Natalie Foster, PharmD.
- Daniel Vandersand, R.Ph.
- Elaina Wolzak, R.Ph.
- Barbara Wood, R.Ph.

### **Board Operations**



#### Office Activities

The Board office received/responded to 6,057 telephone calls during FY24, representing a 22.8% increase from FY23. Board Inspectors responded to 419 calls. Major topic areas for office calls are identified below:



<sup>\*</sup> Pharmacist category includes licensing, continuing education and audit related questions.

<sup>\*\*</sup>COVID-19 related calls may have also been recorded in other categories (e.g. Law/Legal/Compliance/Immunizations/Pharmacy/etc.

### **Board Operations**

#### **Education/Training**

As part of its ongoing efforts to promote voluntary compliance, the Board hosted the following educational programs in FY24 (participants were awarded free continuing education credit):

- 2023 Legislative Update
- 2023 Compliance Update/Inspector Q&A
- 2023 Missouri PDMP Update
- 2024 New Graduate/MPJE Update
- 2024 MO HealthNet Pharmacy Program Update

#### Legislative Proposals

The following legislative proposal was approved by the Board for the 2024 legislative session:\*\*

 Pharmacist Patient-Care Services: Allows pharmacists to order and administer medication as approved or authorized by the U.S. Food and Drug Administration (FDA) to address a public health need during a state/ federally declared public health emergency, or as authorized by the Missouri Department of Health and Senior Services to address a public health need.

#### **Gold Certificates**

The following individuals received Gold Certificates during FY24 representing fifty (50) years of licensure as a Missouri pharmacist:

- Karolyn J. Bryan
- Janet K. Cochran
- Raymond R. Dale, Jr.
- Bruce W. Eilers
- Melissa A. Graham
- Raymond G. Hunter
- James E. Kerr
- Joseph L. Lafiore
- Beth S. Metcalf
- Robert L. Myers

- Ronald H. Myers
- Harry P. Trummer
- Jack R. Vallandingham, Jr.
- Robert J. Winberg
- Fred M. Tichy
- Roy L. Wheeler
- Richard L. Seibert
- Robert A. Shaw
- Randy N. Charles

<sup>\*\*</sup> Legislative proposals are subject to Governor approval.

### **Financial Summary**



#### Financial Overview:

The Missouri Board of Pharmacy's appropriation for the fiscal year ending June 30, 2024, was as follows:

Personal Service \$ 1,462,855.00 Expense and \$ 1,420,808.00

Equipment

Criminal History Fund \$ 5,000.00 Transfers\* \$ 1,369,084.00 \$ 4,257,747.00

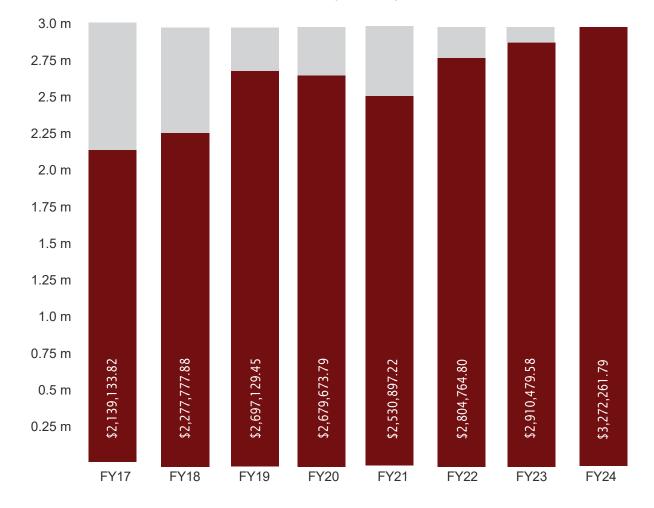
Of the amount appropriated, the Board expended \$3,272,261.79 in FY24 as follows:

Personal Service \$ 1,392,636.17 (43%) Expense and \$ 722,350.69 (22%)

Equipment

Transfers\* \$ 1,157,274.93 (35%)

FY24 expenditures increased 12.43% as reflected below. The increase was primarily related to additional personal service costs related to the statewide employee salary plan:



<sup>\*</sup>Transfers include costs/transfers for rent, the Division of Professional Registration, IT transfers, licensee refunds, attorney general services, Administrative Hearing Commission, DIFP Allocated Expenses and OA Allocated Expenses.

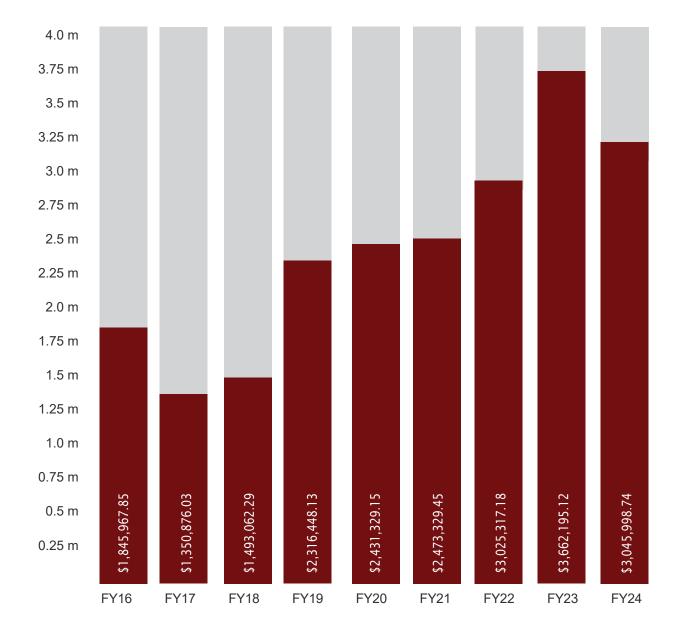
### **Financial Summary**



#### Revenue Received:

The Board of Pharmacy is statutorily obligated to establish fees as necessary to administer the provisions of Chapter 338, RSMo. Section 338.070, RSMo, provides fees must be appropriate so that revenue does not substantially exceed the cost and expense of administering Chapter 338.

Board revenue decreased in FY24 by 16.8% to \$3,045,998.74, in contrast to an uncharacteristic revenue increase in FY23 related to new application revenue affiliated with a national chain expansion. The decrease aligned with previous revenue history:





#### **Licensing Summary**

Pursuant to Chapter 338, RSMo, the Board licenses and regulates pharmacists, intern pharmacists, pharmacy technicians, pharmacies, drug distributors, drug outsourcers and third-party logistics providers.

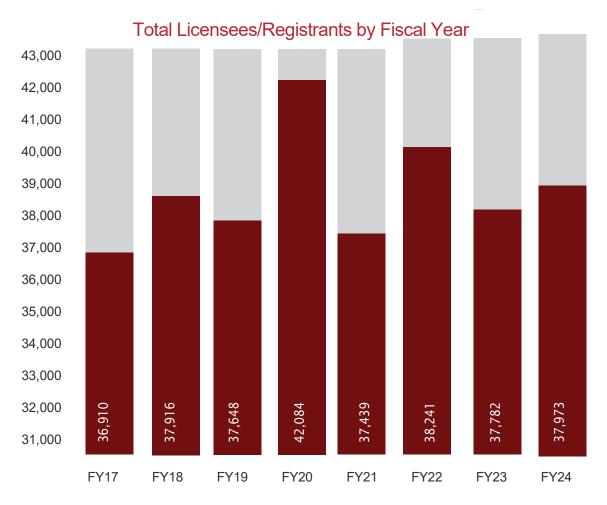
The Board's total licensee/registrant count remained consistent with 37,973 licensees/registrants at the close of the fiscal year (37,688 active/285 inactive), as reflected below:

LICENSING TOTALS	
Drug Distributors (licensed & temporary)	1,281 (-4.6%)
Drug Distributor Manufacturer Registrants	119 (+19%)
Drug Outsourcers	48 (-2%)
Intern Pharmacists	1,337 (+5.7%)
Pharmacists (active and inactive)	12,277 (+3.75%)
Pharmacists (temporary)	10 (- 9%)
Pharmacies (instate, non-resident and temporary)	2,805 (-1.3%)
Pharmacy Technicians	20,147 (23%)
Third-Party Logistics Provider (licensed & temporary)	249 (+3.3%)
TOTAL	37,973 (-0.5%)

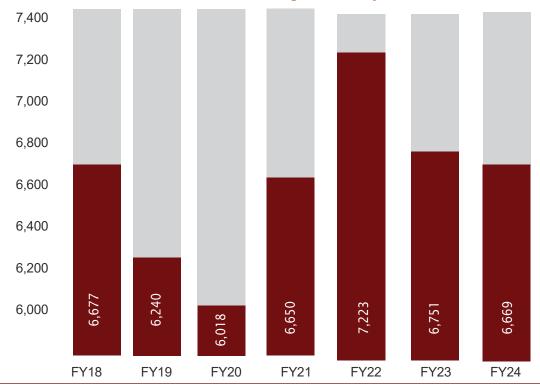
New licensees/registrations remained stable with a total of 6,669 new licensees/registrants issued in FY24 (-1.2%) as reflected below:

- Drug Distributors (91, +2.2%)
- Drug Distributor Registrants (28, +366.6%)
- Drug Outsourcers (5, No Change)
- Intern Pharmacists (322, -10.3%)
- Pharmacies (233, -33.4%%)
- Pharmacists (Active and Inactive) (444, -2.8%)
- Pharmacy Technicians (5,510, +1.3%)
- Temporary Pharmacists (8, -12.5%)
- Third-Party Logistics Providers (28, -28.2%)



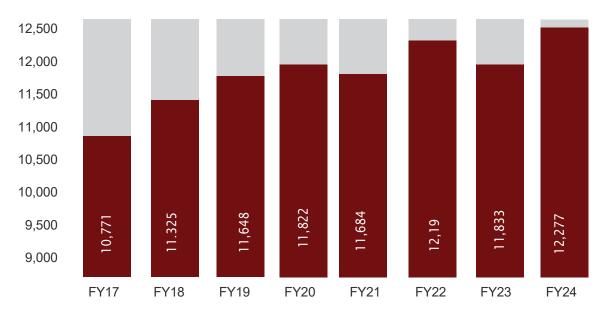






#### Pharmacists:

Total licensed pharmacists increased by 3.75%:



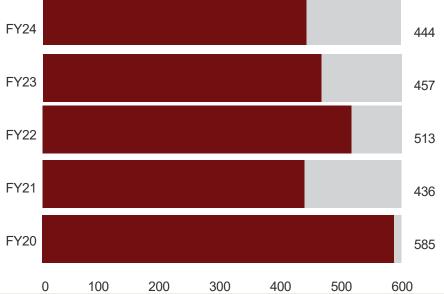
Active vs. inactive Missouri pharmacists are reflected below (resident and non-resident):

Active Licensees	11,992
Inactive Licensees	285
TOTAL LICENSED PHARMACISTS	12,277

<sup>\*\*</sup>Inactive pharmacists are not authorized to practice in Missouri but remain licensed. Pharmacists are only allowed to go inactive during the renewal period.

#### Number of New Pharmacist Licenses Issued

Newly licensed pharmacists remained stable with a minor 2.8% decrease. The decrease was lower than the 10.9% decrease in FY23 but represents the second decrease in successive fiscal years:





#### Pharmacists Residing in Missouri

No significant changes occurred in actively licensed resident vs. non-resident pharmacists. Approximately 60.4% of pharmacists reported a Missouri address as reflected below:

Resident Pharmacists	7,245
Non-Resident Pharmacists	4,747
Total Missouri Resident Pharmacists	11,992

#### Administration & Immunizations:

Pursuant to § 338.010, RSMo, pharmacists are authorized to administer medication by prescription order and to administer vaccines authorized by §338.010, upon filing a Notification of Intent with the Board. At the end of FY24:

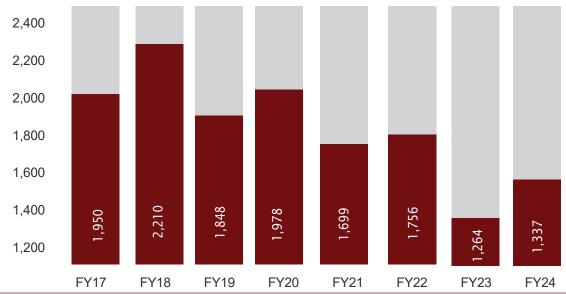
- 3,591 pharmacists were authorized to administer medication by prescription, representing a 13% increase and reversing the 12% decrease in FY23.
- 3,817 pharmacists were authorized to administer immunizations under § 338.010, representing a similar 10% increase.

#### **Medication Therapy Services:**

Section 338.010, RSMo, authorizes the Board to issue a Certificate of Medication Therapeutic Plan Authority (MTS certificate) which allows pharmacists to provide medication therapy services. A total of 4,160 pharmacists held a MTS certificate at the end of FY24 (+8%).

#### Intern Pharmacists:

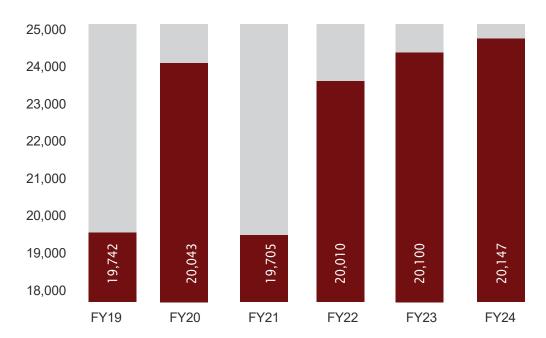
Intern pharmacists increased by 5.7%, in contrast to the 28% decrease in FY23. However, newly licensed intern pharmacists decreased by 10.3% (322 new licensees). Significantly, total licensed intern pharmacists and newly licensed interns have decreased by 36% and 31.6% respectively since FY20. These decreases are consistent with the nationwide decline in pharmacy school students reported by the American Association of Colleges of Pharmacy.





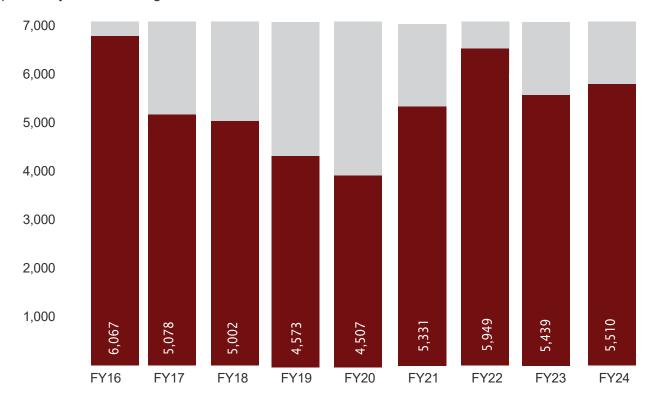
#### Pharmacy Technicians:

Registered pharmacy technicians remained consistent with a minor 0.44% increase.



#### New Pharmacy Technician Registrations Issued

New pharmacy technician registrants remained stable with a 1.2% increase:



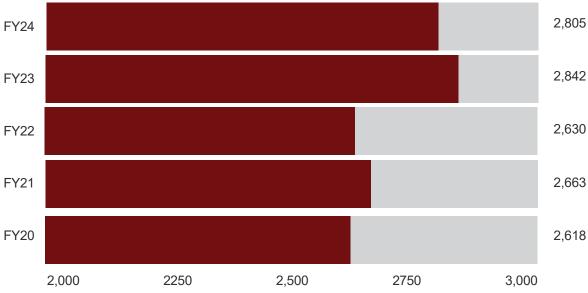


#### Pharmacy Summary:

PHARMACY PERMIT TOTALS					
Instate Pharmacies	1,427				
Non-Resident Pharmacies	1,376				
Temporary Pharmacies	2				
TOTAL	2,805				

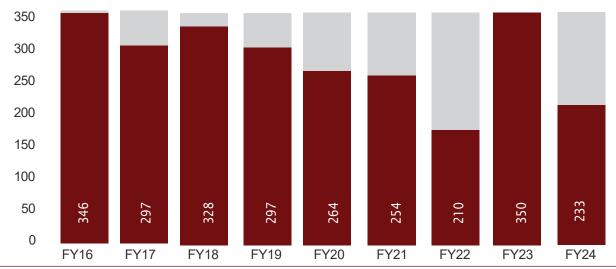
Total pharmacies decreased by 1.3%. In-state pharmacies decreased by 1.1%; Non-resident pharmacies increased by 3.6%.

#### Pharmacy Permitholders by Fiscal Year



#### **New Pharmacy Permits Issued**

New pharmacy permits decreased by 33.4%, reversing an uncharacteristic 66.6% increase in FY23 attributable to new applications submitted by a national chain to accommodate nationwide shared service/central fill activities.





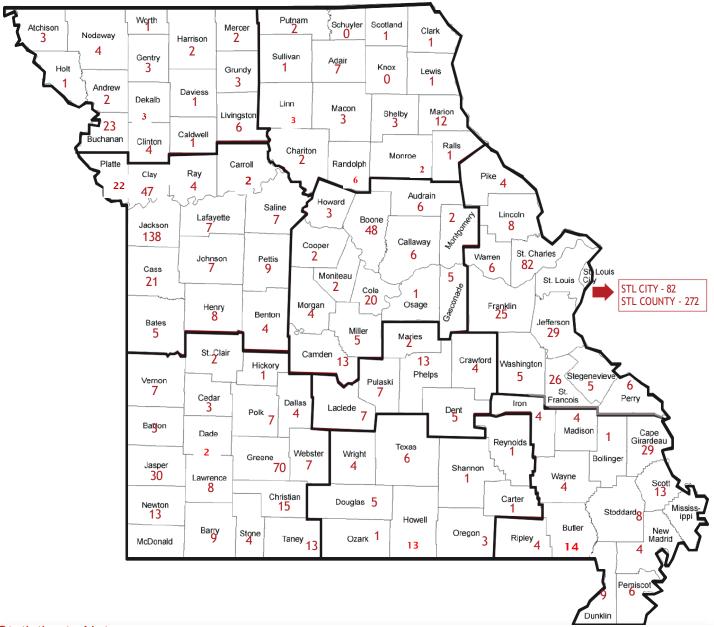
#### Pharmacy Permits by Classification\*

(The below totals will not equal the total # of licensed pharmacies. Pharmacies may hold multiple classifications and could be reflected in more than one category).

(Pharmacies by Classification)	
Class A: Community/Ambulatory	2,184
Class B: Hospital Pharmacy	177
Class C: Long-Term Care	927
Class D: Nonsterile Compounding	781
Class E: Radiopharmaceutical	37
Class F: Renal Dialysis	10
Class G: Medical Gas	9
Class H: Sterile Compounding	390
Class I: Consultant Services	32
Class J: Shared Services	1,436
Class K: Internet	46
Class L: Veterinary	67
Class M: Specialty (Bleeding Disorder)	139
Class N: Automated Dispensing System (Health Care Facility)	23
Class O: Automated Dispensing System (Ambulatory Care)	1
Class P: Practitioner Office/Clinic	2
Class Q: Charitable Pharmacy	1
Class R: Remote Dispensing Site Pharmacy	9



#### Missouri Pharmacies by County



#### Statistics to Note:

- Two Missouri counties do not have a licensed pharmacy (Schuyler, Knox)
- Sixteen (16) counties have only (1) licensed pharmacy: Bollinger, Caldwell, Carter, Clark, Daviess, Hickory, Holt, Lewis, Osage, Ozark, Ralls, Reynolds, Scotland, Shannon, Sullivan, and Worth
- The following nineteen (19) counties/areas experienced a decrease in licensed pharmacies in FY24:
  - Audrain (-1)
  - Barry (-1)
  - Bates (-1)
  - Clinton (-1)
  - Clay (-1)\*
  - Cole (-1)



- Greene (-4)\*
- Howell (-1)
  Jackson (-6)\*
  Lawrence (-1)
  Laclede (-1)
  Macon (-1)

- Mississippi (-1)
- Platte (-1)
- Polk (-1)\*
- Pulaski (-1)
- Taney (-1)
- Webster (-1)
- Wright (-1)

<sup>\*</sup>Counties also declined in FY 23.

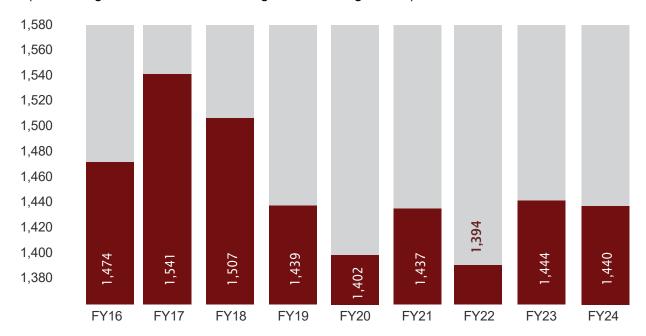


#### **Drug Distributor Summary:**

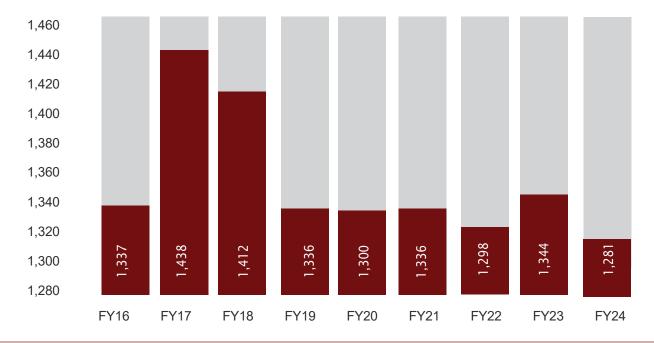
All in-state drug companies that ship/transfer legend pharmaceuticals or drug-related devices are required to be licensed as a Missouri drug distributor. Additionally, out-of-state drug companies or manufacturers that ship/transfer legend drugs or drug related devices into Missouri must hold a Missouri drug distributor license.

#### TOTAL DRUG DISTRIBUTORS & DRUG DISTRIBUTOR REGISTRANTS BY FY

Total licensed drug distributors and drug distributor registrants remained consistent with a minor 3% decrease (1,281 drug distributors and 119 drug distributor registrants).

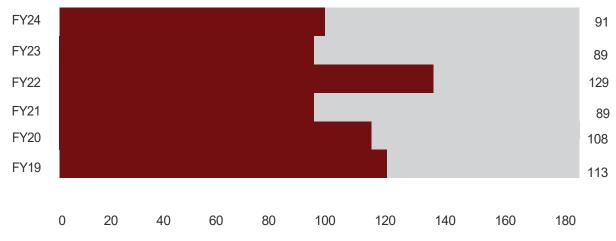


#### TOTAL DRUG DISTRIBUTORS BY FY



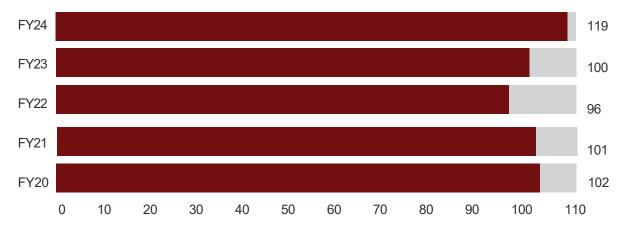
#### NEW DRUG DISTRIBUTORS LICENSED

Newly licensed drug distributors remained consistent with a slight 2.2% increase:



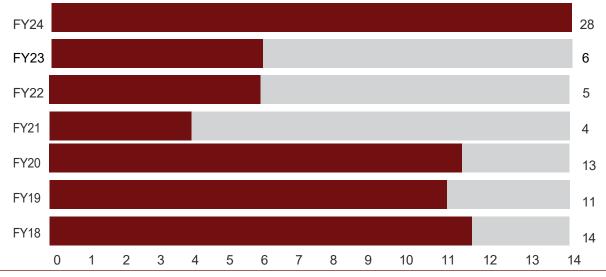
#### TOTAL DRUG DISTRIBUTOR REGISTRANTS BY FY

Total drug distributor registrants increased by 19%:



#### **NEW DRUG DISTRIBUTOR REGISTRANTS**

The number of new drug distributor registrants increased but still remained historically low:





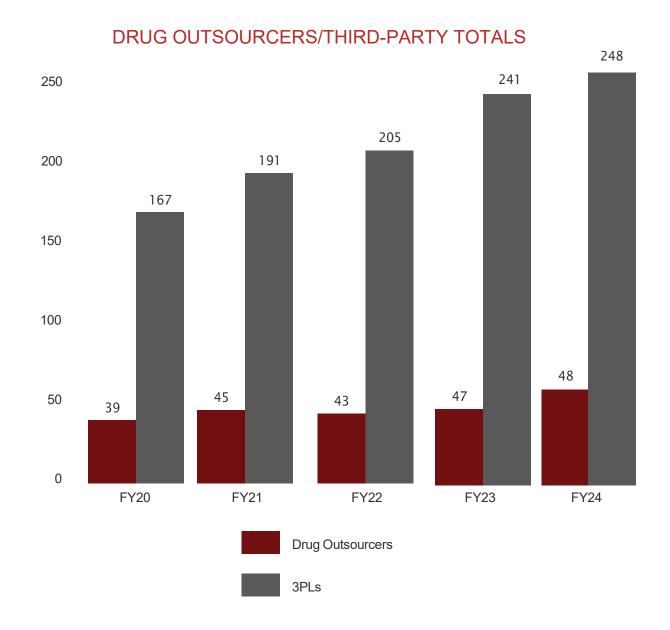
#### DRUG OUTSOURCERS/THIRD-PARTY LOGISTICS PROVIDERS

Total drug outsourcer and third-party logistics provider (3PL) licenses remained consistent in both categories with minimal change:

- Total 3PL licensees increased by 3.3% [241 (FY23); 249 (FY24)]
- Total drug outsourcers increased by 2.1% [47 (FY23); 48 (FY24)]

New applicants for both license classes remained historically low:

- New 3PL licensees decreased by 28% [FY23 (39); FY24 (28)]
- New drug outsourcer licensees were unchanged with five (5) licensees in both FY23 and FY24



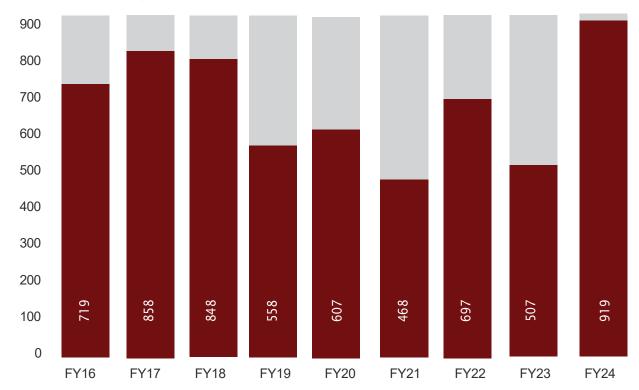
### **Complaint Summary**



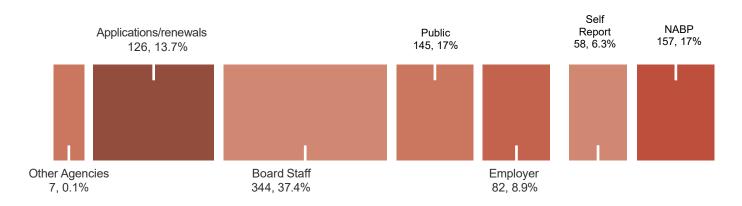
#### **Complaint Summary**

All matters investigated or officially reviewed by the Board are recorded as complaints and processed according to Board procedures. The Board received/opened 919 new complaints in FY24, representing an 81.2% increase from FY 23. The increase is partially attributable to pharmacist continuing education audit cases opened after the FY23 pharmacist renewal year (288, 31.3%). No tax compliance cases/complaints were referred from the Missouri Department of Revenue during FY24.

#### Complaints Handled by FY



#### Complaints by Source



### **Complaint Summary**



#### FY24 COMPLAINTS BY CATEGORY

Adulterated Drugs	1
Advertising or Marketing	2
Audit Finding (Continuing Education)	288
Compounding	11
Confidentiality/HIPAA	3
Criminal History	6
Disciplinary Action in Another State	228
Dispensing Error	34
Drug Distribution	1
Drug Diversion	24
Drug Losses	1
Fraudulent Prescription	4
Fraud - Unspecified	3
Immunization/Administration	10
Impairment/Addiction	13
Improper Controls/Security	65
Improper/Unauthorized Dispensing	22
Incompetence	4
Inspection Violations	3
Insurance Fraud	2
Licensure Applicant	98
Other	2
Mandatory Reporting Violation	2
Pharmacy Permit Violations	3
Prescription Transfers	5
Recordkeeping	1
Sexual Misconduct	1
Theft (Non-drug)	20
Unlawful Drug Use	1
Unlicensed Activity	37
Unprofessional Conduct	20
Unsanitary Conditions	1
Violation of Discipline	3
TOTAL	919

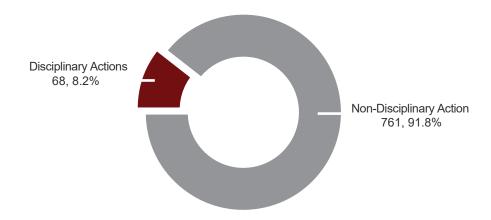
### **Complaint Summary**



#### **COMPLAINT DISPOSITIONS**

The Board issued final dispositions on 829 complaints/cases in FY24. All of the closed complaints/cases were non-tax related.\*\*

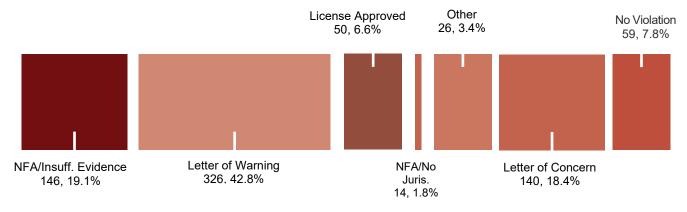
#### (Non-Tax Related Complaint Dispositions)



<sup>\*\*</sup>Dispositions include complaints received in prior fiscal years but finally determined in FY24. As a result, complaint dispositions in FY24 will not equal the number of new complaints received.

#### SUMMARY OF NON-DISCIPLINARY COMPLAINT RESOLUTIONS:

The following action was taken in the 761 non-tax related complaints closed without disciplinary action in FY24 (see Disciplinary Action section for disciplinary information):

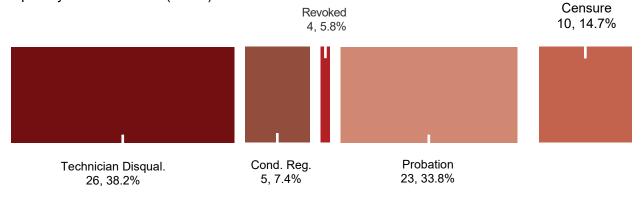


<sup>\*</sup> Other: Closed (14), Closed but Flagged for Future Review (4), Surrender (7), Voluntary Compliance Agreement (1).



#### **Summary of Disciplinary Action**

Board related disciplinary actions in FY24 remained consistent with sixty-eight (68) practice related disciplinary actions issued (+1.49):



#### **DISCIPLINARY ACTIONS BY CATEGORY**

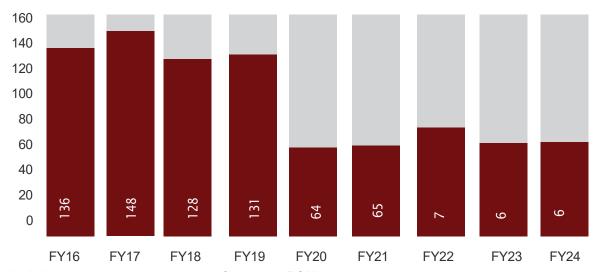
Drug Distributors Probated	4
Drug Distributors Censured	4
Intern Licenses Revoked	2
Pharmacist Licenses Censured	3
Pharmacist Licenses Probated	9
Pharmacist Licenses Revoked	2
Pharmacy Permits Censured	3
Pharmacy Permits Probated	10
Technicians Disqualified	26
Technicians Placed on Conditional Registration	5
TOTAL	68



#### PRACTICE RELATED DISCIPLINARY ACTIONS \*

Thirty-one (31) pharmacy technicians, 14 pharmacists, 13 pharmacies, 8 drug distributors and 2 intern pharmacists were disciplined for practice-related issues during FY24. Total disciplinary actions remained consistent with FY 23 (+1.49%).

#### (Total Practice-Related Disciplinary Actions by FY)

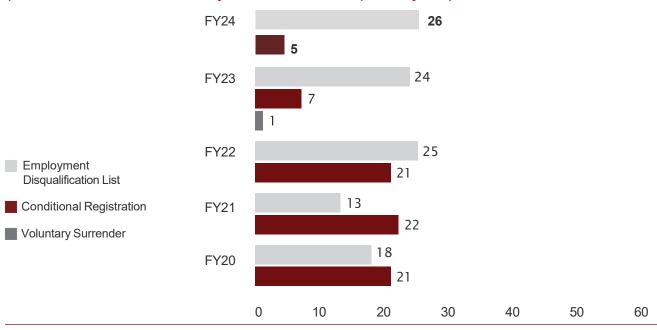


<sup>\*</sup> Does not include tax suspensions pursuant to § 324.010, RSMo.

#### PHARMACY TECHNICIAN DISCIPLINE

Thirty-one (31) pharmacy technicians were disciplined for practice-related reasons, comprising 45.5% of all practice-related disciplinary actions issued by the Board.

#### (Practice Related Pharmacy Technician Discipline by FY)





# GROUNDS FOR TECHNICIAN EMPLOYMENT DISQUALIFICATION (Cause for EDL / # Disciplined)

- Criminal History (5)
- Diversion/Attempted Diversion (11)
- Fraudulent Prescriptions (2)
- Illegal Drug Usage/Positive Drug Test (5)
- Theft (Non-Drug Related) (3)

# GROUNDS FOR TECHNICIAN CONDITIONAL REGISTRATION (Cause for CR / # Disciplined)

- Criminal History (1)
- Improper Dispensing (1)
- HIPAA/Patient Confidentiality (1)
- Theft (Non-Drug Related) (2)

#### PHARMACIST DISCIPLINE BY FY:

Pharmacist practice-related discipline increased by 27.2% from FY24, although overall pharmacist disciplinary totals remained historically low.

	FY17	FY18	FY19	FY20	FY21	FY22	FY23	FY24
Censure	6	3	11	5	2	6	1	3
Probation	13	15	10	6	8	6	5	9
Suspension	0	0	0	0	0	0	0	0
Suspension/Probation	0	1	0	2	5	1	2	0
Revocation	1	1	1	2	1	1	1	2
Voluntary Surrender (treated as discipline)	4	1	4	1	2	4	2	0
TOTAL	24	21	26	16	18	18	11	14



#### PHARMACY DISCIPLINE BY FY

Pharmacy discipline decreased by 29.4% as reflected below:

	FY19	FY20	FY21	FY22	FY23	FY24
Censure	0	1	0	2	6	3
Probation	15	5	6	7	11	9
Revocation	0	0	0	0	0	0
Voluntary Surrender	1	2	0	0	0	0
TOTAL	16	8	6	9	17	12

#### DRUG DISTRIBUTOR DISCIPLINE BY FY

Total drug distributor/drug distributor registrant disciplinary actions remained historically low, as reflected below:

	FY19	FY20	FY21	FY22	FY23	FY24
Censure	0	0	0	1	3	4
Probation	6	1	3	3	3	4
Voluntary Surrender	0	0	0	0	0	0
TOTAL	6	1	3	4	6	8

### Inspections/Investigations

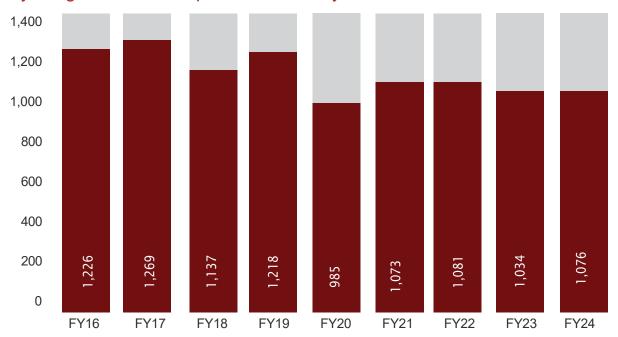


#### Inspection/Investigation Summary

The Board conducts new and routine inspections of all Missouri located pharmacies, drug distributors, drug outsourcers and third-party logistics providers. Board inspectors also conduct investigations as assigned.

- 1,076 regulatory inspections were conducted during the fiscal year, representing a 4% increase from FY23. Total completed investigations decreased by 13.6% to 246 completed investigations, partially attributable to new inspection staff in training.
- 884 pharmacies, 169 drug distributors, 2 drug outsourcers, and 21 third-party logistics providers were inspected during the fiscal year. Seventeen (17) drug distributors and two (2) third-party logistics providers were exempt from inspection as state-owned facilities or as authorized by 20 CSR 2220-5.040/20 CSR 2220-8.050 for facilities inspected by the U.S. Food and Drug Administration.

#### Pharmacy/Drug Distributor Inspection Summary



#### INSPECTION FINDINGS

At the conclusion of an inspection, an inspector may initiate one of the following resolutions:

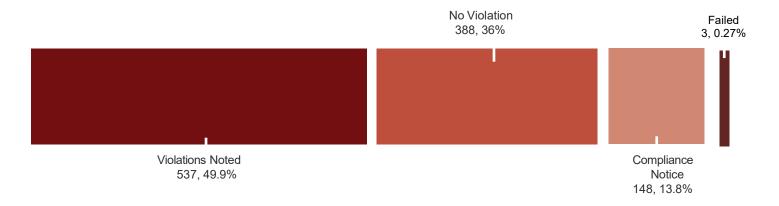
- Observation Report: Issued if no compliance issues are identified at the time of inspection or if compliance violations are noted that can generally be corrected and do not require further review/documentation.
- Compliance Notice: Issued if compliance concerns are discovered that require official documentation of corrective measures or in instances of multiple or repeat compliance violations.
- Quality Assurance Report: Issued if there is a specific question regarding the dispensing/handling
  of a particular prescription and/or drug.
- Investigation: An investigation may be initiated during an inspection if additional factual information may be necessary to assess compliance.

### Inspections/Investigations



#### **FY24 INSPECTION RESULTS\***

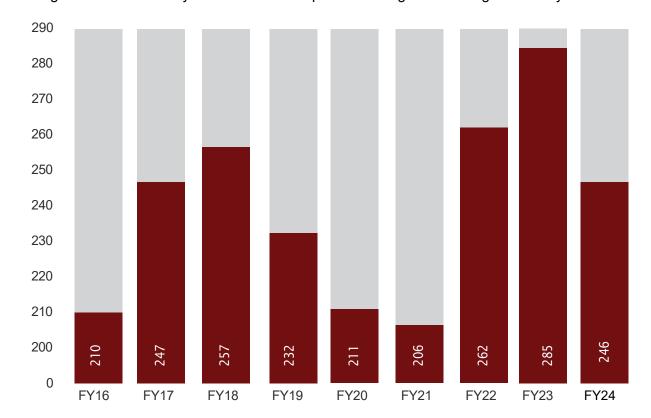
Approximately 63.6% of Board inspections resulted in violations noted or a compliance notice being issued as reflected below:



Inspection results in each category remained statistically consistent (e.g., no violation, violations noted, compliance notices).

#### **FY24 INVESTIGATION SUMMARY**

Total investigations decreased by 13.6% to 246 completed investigations during the fiscal year.



<sup>\*</sup> Includes inspection results for follow-up inspections and investigations.

### **Compounded Drug Testing**



#### **Testing Summary**

Pursuant to § 338.150, RSMo, the Board operates a program to test drug preparations compounded by pharmacies. All preparations are tested for potency and, if applicable, sterility and endotoxins. The tables listed below are for the fiscal year ending June 30, 2024:

Dosage Form	Tests Performed
Capsule	20
Topical cream/ointment/gel	19
Oral suspension/solution	10
Injection	3
IV Solution	2
Ophthalmic Solution	1
Sublingual tablet	1
Suppository	1
Tablet	1
Troche	1

Test Results	Tests Performed	Percentage
Satisfactory	42	71.2
Unsatisfactory	17	28.8
Total	59	100%

All unsatisfactory results were related to potency failures. An acceptable potency range is considered +/- 10% of the expected potency, unless a U.S.P. monograph states a different range for a specific preparation. Failing potency results ranged from 40.6% to 126.7%. Pharmacies are notified of unsatisfactory results and asked to complete a quality assurance review of their compounding practices and provide a corrective action plan.

Preparations With Unsatisfactory Results
Bi-Est
Bi-Est/Progesterone
Bi-Est/Progesterone/DHEA
Bi-Est/Progesterone/Testosterone
Diltiazem/Lidocaine
Hydroxychloroquine/Zinc gluconate
Ivermectin/Vitamin D3
Ketamine/Gabapentin/Diclofenac Sodium/Lidocaine HCl
Nifedipine/Lidocaine
Semaglutide/Cyanocobalamin
Testosterone

### Rulemaking



#### Rule Changes

The Board continued its ongoing review of Board rules to ensure appropriate and consistent regulation and to adopt a standards of practice approach focused on:

- Establishing standards of practice to ensure patient safety
- Eliminating unnecessary regulatory requirements, and
- · Maximizing pharmacist skill, training and education to enhance patient access to care

The following rules were promulgated/amended by the Board in FY24:

20 CSR 2220-2.175	Well-Being Program	Updated administration and participation requirements for the Board Well-Being Program and participants
20 CSR 2220-2.400	Compounding Standards of Practice	Updated definition of essential copies of a commercially available product; General update of rule language
20 CSR 2220-2.410	Class B Hospital Pharmacy Compounding for Drug Shortages	Established allowances/requirements for hospital pharmacies compounding preparations during a shortage to increase patient medication access
20 CSR 2220-2.900	Class N: Health Care Facility Automated Dispensing Systems	Updated requirements for Class N automated dispensing systems located within a licensed health care facility and used to dispense medication to resident patients, pursuant to a patient-specific prescription under the Board's jurisdiction
20 CSR 2220-2.910	Class O: Automated Dispensing Systems (Ambulatory Care)	Authorized use of Class O automated systems used to prepare/dispense prescriptions for patient retrieval



#### Rx Cares Program Overview

The Missouri General Assembly enacted § 338.710 in 2017 which created the Rx Cares for Missouri Program within the Board of Pharmacy to promote medication safety and to prevent prescription drug abuse, misuse and diversion in Missouri. Rx Cares Program funding is appropriated annually by the Missouri General Assembly. The Board expended \$ 368,430.88 in FY24 on the following Rx Cares program activities:

#### **Rx Cares Medication Destruction Program**

The Rx Cares program was enacted simultaneously with § 338.142, RSMo, which granted the Board authority to establish a drug take-back program for controlled substances, in consultation with the Missouri Department of Health and Human Services. The Board subsequently established the statewide Rx Cares for Missouri Medication Destruction and Disposal Program for the collection of unused/unwanted medication. The medication destruction/disposal program plays a critical role in combating the opioid epidemic by providing safe options for patient disposal of unused or unwanted medication.

Pursuant to state contract, the medication destruction/disposal program is managed/operated by Sharps Compliance® under the supervision of the Board. Eligible program participants include:

- A licensed Missouri pharmacy or drug distributor
- A licensed healthcare provider authorized to prescribe controlled substances
- A hospital, office, clinic, or other medical institution that provides health care services
- · A federal, state, local, or municipal public health, law enforcement, or other governmental agency, or
- A higher education institution located in Missouri that is accredited by a national or regional accrediting body recognized by the United States Secretary of Education. [20 CSR 2220-2.990]

Board approved program participants are provided a medication collection receptacle that complies with state and federal controlled substance laws. Collected medication can be mailed/submitted to an approved Sharps Compliance® vendor up to twelve (12) times per year at no cost to the participant.

- Expenditures for the medication destruction/disposal program totaled \$ 181,499.53 in FY24
- One-hundred and twenty-four (124) entities were approved to participate in the medication destruction/disposal program in FY 24, including, pharmacies, hospitals, and local law enforcement agencies\*\*
- Approximately 14,650.4 pounds of unwanted medication were destroyed in FY24 (-5.5%); A total of 51,476.96 pounds of unwanted medication have been destroyed since program inception.\*\*

<sup>\*\*</sup>Data as of July 25, 2024.



#### **Rx Cares Grant Program**

Section 338.710, authorizes the Board to expand, allocate or award funds appropriated to the Board to provide programs or education to promote the Rx Cares Program goals. The following organizations received Rx Cares grants funding in FY24:

Recipient	Description	Funding Amount
En-Vision America	Statewide program to increase health literacy and patient safety for patients who are blind, visually impaired or print impaired by enabling pharmacies to provide accessible prescription labels.	\$80,000
Ridge Maude Drug Corporation (dba Key Drugs Pharmacy)	Increase patient safety for patients who are blind, visually impaired or print impaired by providing ScriptTalk <sup>®</sup> digital prescription label reading devices to Southeast Missouri patients.	\$29,062.45
Tim Mitchell Medical	Patient safety campaign in Newton and McDonald Counties. Program activities include: (1) Utilizing Community Health Workers to train/educate patients on overdose risks and safe medication disposal, (2) Deploying Missouri licensed pharmacists to provide medication reviews and medication safety education to the senior community and local school districts, (3) Participating in medication take-back initiatives in coordination with local law enforcement agencies, and (4) Providing medication destruction packets and lock boxes for patient storage/destruction of high-risk medications.	\$40,800.40
Washington University	Interdisciplinary research to investigate the feasibility of community health worker-pharmacy led interventions to increase patient engagement and retention in innovative strategies of harm reduction. Grant funding includes a pilot cluster randomized hybrid type II clinical trial. Project operated in collaboration with UMKC, St. Louis College of Pharmacy, Washington University, and the Missouri Pharmacy Association.	\$37,068.50
	TOTAL AWARDED GRANT FUNDING	\$186,931.35

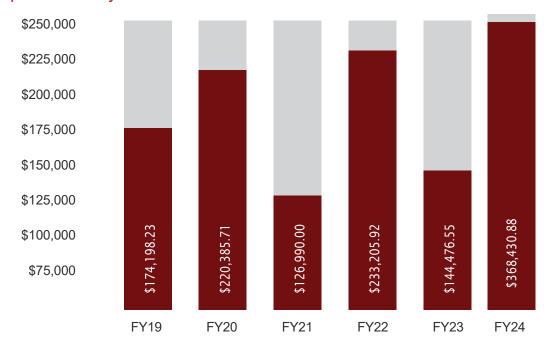


### **Rx CARES FOR MISSOURI FY24 FINANCIAL SUMMARY**

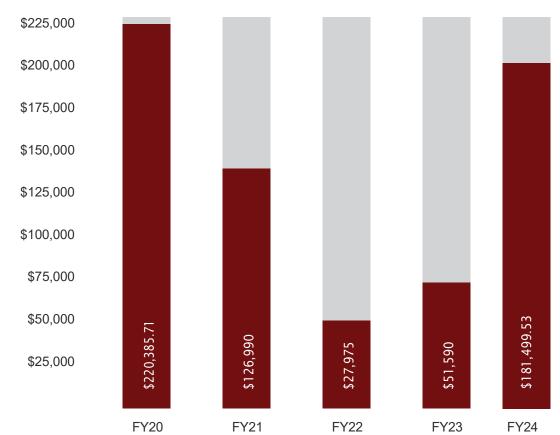
FY24 Appropriation		
Legislative Appropriation	\$ 750,000.00	
Adjustments/Refunds	\$ -	
		\$ 750,000.00
Funds Expended**		
En-Vision America	\$ 80,000.00	
Ridge Maude Drug Corporation (dba Key Drugs Pharmacy)	\$ 29,062.45	
Tim Mitchell Medical	\$ 40,800.40	
Sharp's Compliance (Medication Destruction Program)	\$ 181,499.53	
Washington University	\$ 37,068.50	
Total Expenses		\$368,430.88



#### Rx Cares Expenditures by FY



#### Rx Cares Medication Destruction Funding



### **BOARD OF PHARMACY**



573.751.0091 Telephone 573.526.3454 Fax 800.735.2966 TTY 800.735.2466 Voice Relay





